ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote incurs objection under clause 6 of rule XX.

The House will resume proceedings on postponed questions at a later time.

FDA REAUTHORIZATION ACT OF 2017

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2430) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2430

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''FDA Reauthorization Act of 2017''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2017''.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Section 736(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is amended—

(A) in the matter preceding paragraph (1), by striking ''fiscal year 2013'' and inserting ''fiscal year 2018'';

(B) in the heading of paragraph (1), by striking ''AND SUPPLEMENT'';

(C) in paragraph (1), by striking ''or a supplement'' and ''or supplement'' each place either appears;

(D) in paragraph (1)(A)—

(i) in clause (i), by striking ''(c)(4)'' and inserting ''(c)(5)''; and

(ii) in clause (ii), by striking ''A fee established'' and all that follows through ''are required.'' and inserting the following: ''A fee established under subsection (c)(5) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval.'';

(E) in the heading of paragraph (1)(C), by striking ''OR SUPPLEMENT'';

(F) in paragraph (1)(F)—

(i) in the heading, by striking ''OR INDICATION''; and

(ii) by striking the second sentence;

(G) by striking paragraph (2) (relating to a prescription drug establishment fee);

(H) by redesignating paragraph (3) as paragraph (2);

(I) in the heading of paragraph (2), as so redesignated, by striking ''PRESCRIPTION DRUG PRODUCT FEE'' and inserting ''PRESCRIPTION DRUG PROGRAM FEE'';

(J) in subparagraph (A) of such paragraph (2), by amending the first sentence to read as follows: ''Except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(5) for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year.'';

(K) in subparagraph (B) of such paragraph (2)—

(i) in the heading of subparagraph (B), by inserting after ''EXCEPTION'' the following: ''FOR CERTAIN PRESCRIPTION DRUG PRODUCTS''; and

(ii) by striking ''A prescription drug product shall not be assessed a fee'' and inserting ''A prescription drug program fee shall not be assessed for a prescription drug product''; and

(L) by adding at the end of such paragraph (2) the following:

''(C) LIMITATION.—A person who is named as the applicant in an approved human drug application shall not be assessed more than 5 prescription drug program fees for a fiscal